

CLEVELAND, OH [September 2, 2011] – The Advanced Platform Technology (APT) Center, a Center of Excellence of the U.S. Department of Veterans Affairs (VA), announced today that the U.S. Food and Drug Administration (FDA) has granted Investigational Device Exemption (IDE) approval to evaluate the feasibility of its peripheral nerve interface for sensory feedback in upper extremity prostheses.

This study is an essential step in the development of new techniques to enhance the prosthesis function for individuals with limb loss. The hypothesis-driven research project will determine whether peripheral nerve stimulation with extraneural, multi-channel cuff electrodes provides appropriate sensory feedback to improve performance of a myoelectric prosthesis compared to no sensory feedback. With support from the Department of Veterans Affairs, the APT Center looks forward to enrolling up to 5 participants into its clinical study at the Louis Stokes Cleveland Department of Affairs Medical Center in the United States.

The proposed research offers a distinct benefit to the field of sensory restoration since the study will look at how the neural stimulation is perceived and incorporated into the self-awareness of the participants. The utility of perception on prosthesis control will be evaluated during activities of daily living.

“Selectively producing different natural sensations in the phantom hand associated with real interactions of the prosthesis, such as sensing the pressure applied during holding of an object or the position of the fingers is a possible outcome of such work”, said Dustin Tyler, PhD BME, Principal Investigator of the study and Associate Director of the VA APT Center, as well as Associate Professor of Biomedical Engineering Case Western Reserve University.

The growing need for a new interface between the user and the prosthetic limb

Studies show that amputation is one of the most significant, non-fatal co-morbidities of combat, with incidence rates historically as high as 16% of all admissions to military hospitals, and reportedly increasing. Upper extremity amputation is particularly devastating, in part due to functional deficits and decreased independence. Typically, commercially available myoelectric prostheses do not provide the user with either proprioceptive or sensory feedback, limiting the capabilities even the most mechanically advanced prosthesis.

Advances in nerve interface technology make long-term communication with residual nerves possible. New devices can interact selectively with portions of the nerves and this makes it possible to produce several sensations within the remaining nerves. Once the device activates

the nerve, the user feels like the sensation comes from their actual hand. This is termed the “phantom limb.” Restoring natural sensation can lead to better acceptance of the artificial limb and acceptance as an actual part of the user’s body. This project is one of several approaches currently under investigation to return natural sensation to prosthesis users.

About APT Center

The VA Rehabilitation R&D Center of Excellence in Advanced Platform Technology (APT Center) was established January 2005 in partnership with Case Western Reserve University. This transdisciplinary collaboration represents a critical mass of 30 investigators, fully leveraging capital to translate new concepts (innovation) to a medical device ready for clinical application. Clinicians, investigators, and staff work together to bring clinical needs of disabled veterans to the forefront by adapting cross-cutting foundational technical platforms for advanced prosthetic systems, sensory aids, and other clinical applications.

The principal investigator and his colleagues have developed a wealth of neural interfacing technology, bringing the peripheral nerve interface approach to the forefront of innovation. While originally developed for functional restoration in subjects with spinal cord injury, the technology is directly applicable for natural interfacing in sensory feedback for limb prosthetics.

